

Facility Name:
Effective Date:
Approved By:

VFC PIN:
Annual Review Date:

VACCINE STORAGE AND HANDLING PLAN

This document is a vaccine storage and handling plan to safeguard vaccine supplies and respond to improper vaccine storage and handling events.

VACCINE STORAGE AND HANDLING GUIDELINES

1. STORAGE REQUIREMENTS

Maintain proper temperatures in the refrigerator, 35° through 46°F or 2° through 8°C. Store all varicella-containing vaccine (Varivax, Zoster, ProQuad) at -58° through +5°F or -50° through -15°C. The MMR vaccine can be stored in either the refrigerator or freezer. Storing MMR vaccine in the freezer with MMRV may help prevent inadvertent storage of MMRV in the refrigerator. Diluent should NOT be stored in the freezer.

To help stabilize temperatures in the storage units place plastic containers of water in the refrigerator and cold packs in the freezer. Store vaccine on refrigerator shelves in open containers and away from walls and the back of the unit to allow proper air circulation around the vaccine. Vaccine should never be stored in the door of the refrigerator, vegetable containers/bins (crisper) or on the bottom of the refrigerator. A primary and backup thermometer should be placed in both the refrigerator and freezer unit. The thermometers should be certified calibrated with a certificate of traceability and calibration.

- ☐ Proper temperatures for refrigerator(s) and freezer(s) are posted on unit(s).
- ☐ Bulk water/cold packs are present in the unit.
- ☐ Vaccine is stored in center of unit in open containers to allow for air circulation.
- ☐ Vaccine is not stored in the door of the unit, crisper, or in the bottom of the unit.
- ☐ Primary and backup thermometer is in place in each unit (both refrigerator and freezer).

2. EQUIPMENT /SAFEGUARDS

Post warning signs on the refrigerator and/or on the plug to prevent inadvertent unplugging of the unit. Label fuses and circuit breakers to clearly identify power source to the vaccine storage unit. Do not plug unit into ground fault interrupter (GFI) outlets. When the GFI is tripped the circuit is broken, causing electricity failure to the unit. Do not use an extension cord to plug in the storage unit. Ensure doors are shut tightly.

- ☐ Warning signs (e.g., Do Not Unplug) are posted on vaccine storage units and on the outlet.
- ☐ Fuses and circuit breakers that support vaccine storage units are clearly marked.
- ☐ The vaccine storage unit is not plugged into a GFI outlet or an extension cord.
- ☐ Doors close appropriately and are free from defect.

3. TEMPERATURE MONITORING

A primary and backup thermometer is in place in each unit (both refrigerator and freezer). The designated person checks and records refrigerator and freezer temperatures twice daily (at the beginning and end of each work day) and records the time and name/initials associated with each temperature reading. Storage temperatures should be recorded on a temperature log and maintained for at least 3 years. This is useful to identify the duration of temperature variations. If a temperature outside of the recommended range is found, immediate action should be taken to correct the problem as outlined in the standard operating procedures for improper vaccine storage and handling section. The backup person should review the temperature log at least weekly to ensure proper temperature recording and take action if out of range temperatures are found on the logs during review. Consideration should be given to how power failures or out of range temperature will be identified during non-business hours.

- ☐ Refrigerator and freezer temperatures are checked and recorded on a temperature log twice daily along with staff initials and time of readings. Storage temperature logs are maintained for at least 3 years for each unit.

- ☐ The designated backup person reviews temperature logs at least weekly.
- ☐ Clinic staff is trained to take immediate action if temperatures are out of range.
- ☐ Primary and backup thermometer is in place in each unit (both refrigerator and freezer).

4. VACCINE ORDERING

Health care providers participating in the VFC Program are responsible for ordering and maintaining adequate vaccine inventory for eligible patients and to prevent missed opportunities. The Iowa Department of Public Health, Vaccine for Children Program requires VFC providers to place vaccine orders using the Immunization Registry Information System (IRIS). IRIS contains vaccine order functionality which includes recommended order quantities based on ordering patterns and doses administered data. When placing vaccine orders, review recommended order quantities for each vaccine, total amount of vaccine needed, including combination and single antigen products.

- ☐ Review current inventory / expiration dates and consider seasonal events or specialty clinics.
- ☐ Clinic staff is aware of Economic Order Quantity.
- ☐ Clinic staff is trained regarding vaccine ordering.
- ☐ Do not over-order or stockpile vaccine.
- ☐ Maintain adequate inventory of VFC and private vaccine (if applicable) to eliminate occurrences of borrowing between VFC and private inventories.

5. RECEIVING VACCINE

Develop and post a protocol for accepting vaccine deliveries that indicates who in the practice may accept vaccine shipments to ensure vaccines are stored appropriately and **IMMEDIATELY** after arrival. Train staff how to compare the vaccine received with the vaccine invoice.

Cold and heat indicators should be reviewed immediately to ensure vaccine was maintained at the appropriate temperatures during shipping. Alert the Vaccines for Children (VFC) Program at 1-800-831-6293 if the vaccine is not in proper condition, the number of doses is different than what is on the invoice, or if the lot number is recorded incorrectly on the invoice.

- ☐ Protocol is posted for all staff regarding vaccine deliveries and whom to contact regarding vaccine shipments.
- ☐ Clinic staff ensure vaccine shipments are stored properly immediately upon arrival.
- ☐ Clinic staff is trained how to compare vaccine received to the vaccine invoice and will alert the VFC Program if vaccine doses do not match the invoice or if they are not in proper condition upon arrival.
- ☐ Maintain vaccine packing slips for both VFC and private vaccine inventory for a minimum of three years.

6. VACCINE MANAGEMENT/STOCK ROTATION

Check and rotate your stock monthly or when new vaccine inventory arrives. Ensure vaccine with the most current expiration dates are used first and are in front of vaccines with longer expiration dates.

- ☐ Conduct count of vaccine inventory at least monthly.
- ☐ Rotate vaccine stock regularly; move earliest expiration dates to the front.
- ☐ Check vaccine expiration dates at least monthly.
- ☐ Clinic staff is able to distinguish VFC vaccine from private vaccine.
- ☐ Report VFC vaccine that will not be used and will expire within 2-3 months to the Iowa VFC Program at 1-800-831-6293.

7. BACK-UP SUPPLIES/FACILITY

It is important to have a back-up plan to appropriately store vaccine. Make formal arrangements (memorandum of understanding) with a backup facility to maintain vaccine if your vaccine storage equipment malfunctions or there is a power outage. Train a designated person and backup person at the facility to accept your vaccine if it must be moved. Before moving your vaccine, call the location to ensure their facility is available to store the vaccine (e.g., not damaged due to storms). If the back-up facility is not available contact the other facilities on your backup facility list.

BACK-UP FACILITIES CONTACT INFORMATION

Name of Facility	Primary & Back-up Contact	Contact Phone Number Work/Home/Cell

EMERGENCY CONTACT LIST

List of emergency phone numbers, companies, and points of contact:

<input type="checkbox"/> Electric Power Company:
<input type="checkbox"/> Temperature Alarm Monitoring Company:
<input type="checkbox"/> Refrigerator Repair Company:
<input type="checkbox"/> Transportation to Back-up Storage:
<input type="checkbox"/> Emergency Generator Repair Company:
<input type="checkbox"/> National Weather Service:

FACILITY FLOOR PLAN

Entering vaccine spaces: Describe, when necessary, how to enter the building and vaccine storage spaces in an emergency if closed or after hours. Include a simple floor diagram (does not need to be a blue print) and the locations of:

<input type="checkbox"/> Storage units:
<input type="checkbox"/> Doors:
<input type="checkbox"/> Flash lights:
<input type="checkbox"/> Spare batteries:
<input type="checkbox"/> Light switches:
<input type="checkbox"/> Keys:
<input type="checkbox"/> Locks:
<input type="checkbox"/> Alarms:
<input type="checkbox"/> Circuit breakers:
<input type="checkbox"/> Packing materials:

8. RESPONSE TO IMPROPER VACCINE STORAGE AND HANDLING**ASSESS THE SITUATION**

- Determine the cause of improper vaccine temperatures (e.g., mechanical failure, power outage, natural disaster, human error).
- Store the vaccines at appropriate temperatures. Determine if vaccine should be moved and move if appropriate.
- Record the current temperature of the refrigerator/freezer.
- Mark the vaccine "Do Not Use" so the potentially compromised vaccines can be easily identified and not used until viability of vaccine is determined.
- Collect essential data on the Emergency Vaccine Response Worksheet.
- Call the Iowa Immunization Program (1-800-831-6293)
- Call all manufacturers of affected vaccine(s).

PACK VACCINE

- a. Open refrigerated units only when absolutely necessary and only after you have made all preparations for packing and moving the vaccine to alternative storage site.
- b. Use hard sided coolers with at least 2 inch walls, or portable refrigeration units, to transport vaccine supply.
- c. Pack the refrigerated vaccines first with an adequate supply of cold packs (add packing material so cold packs are not in direct contact with the vaccine). For transport of refrigerated vaccines ice packs should be conditioned by placing them at room temperature for at least 1 hour prior to packing.
- d. The manufacturer of varicella-containing vaccines, Merck, recommends the vaccines (Varivax, Zoster, ProQuad) **NOT** be transported on dry ice. Use of dry ice may subject the vaccines to temperatures colder than -58° F (-50° C). Several companies make portable freezer units.
NOTE: In the event the vaccine must be moved due to emergency situations and a portable freezer unit is not available, Varicella-containing vaccine should be moved in a separate cooler from the refrigerator vaccines. The cooler containing varicella vaccines should be packed with as many ice packs as possible and a thermometer placed in the cooler. The time and temperature must be monitored and recorded until vaccine is stored under proper conditions in an approved storage unit. Once the vaccine has been stored appropriately the Iowa Immunization Program and the manufacturer must be contacted prior to using the vaccine.
- e. Include a thermometer with the vaccine in each cooler to monitor the vaccine temperature during transport.

MOVE VACCINE

- a. If alternative storage is available within your facility transfer vaccine to that storage unit. If not, contact your backup facility to notify them of your refrigerator/freezer failure and the need to store vaccine at their location.
- b. Prior to transporting vaccine, record the time and the temperature of the refrigerator(s) and freezer(s) units. This will provide data on the maximum temperature and duration of exposure of vaccine to inappropriate temperatures.
- c. Conduct an inventory before you transport the vaccine.
- d. Transport the vaccine following proper cold chain procedures for storage and handling.
- e. Isolate and maintain vaccines at appropriate temperatures and do not administer or discard vaccine until you have contacted the Iowa Immunization Program (1-800-831-6293) for consultation.

POST EVENT

Keep exposed vaccine separated from unaffected vaccine and any new vaccine you receive. Maintain vaccines at appropriate temperatures and do not administer or discard any potentially exposed vaccine until you have contacted the Iowa Immunization Program (1-800-831-6293) for consultation.

9. VACCINE WASTAGE

Never assume vaccine is nonviable in the event of a storage problem and handling issue. Contact the Iowa VFC Program immediately (1-800-831-6293) for instructions regarding VFC vaccine. Vaccines determined to be non-viable should be documented appropriately on the Nonviable Vaccine Return Form and reported to the VFC Program Coordinator. Document vaccine loss using appropriate reasons provided in IRIS.

10. STAFFING/TRAINING

Post the Vaccine Storage and Handling Plan on or near the vaccine storage units and ensure all staff is trained regarding the plan. Review the current guidelines for handling of individual vaccines that may include special instructions (e.g., protect from light, shelf life after reconstitution). Understand package inserts for new vaccines before using. Additional references include the Centers for Disease Control and Prevention (CDC), "Vaccine Management: Recommendations for Handling and Storage of Selected Biologicals" and "You Call the Shots, Vaccine Storage and Handling" available at <http://www.cdc.gov/vaccines/ed/youcalltheshots.htm>

- ☐ Vaccine Storage and Handling plan is posted on or near storage unit.
- ☐ All staff is trained on the plan and training is documented (minimum of annually).
- ☐ Staff is trained on guidelines for handling individual vaccines with special instructions.
- ☐ Staff who administers vaccine have read and understand package inserts prior to administering vaccine.
- ☐ Staff has access to Vaccine Storage and Handling Guide and the CDC Epidemiology and Prevention of Vaccine Preventable Diseases (Pink book).

11. DESIGNATED PERSON(S)

Designate a primary and a backup person to:

- ☐ Monitor the operation of the vaccine storage units and systems.
- ☐ Set up and maintain a monitoring/notification system during times of inclement weather or other conditions that would create an interruption of power.
- ☐ Ensure the appropriate handling of the vaccine during a disaster or power outage.
- ☐ Ensure access to the building where vaccines are stored 24 hours per day.

Primary Person:	Phone:
Secondary Person:	Phone:
Additional Staff:	Phone:

EMERGENCY VACCINE RESPONSE PLAN

Post on outside of refrigerator

Vaccine Storage and Handling Staff:

Primary:	Phone:
Secondary:	Phone:
Staff with 24 hour access:	Phone:
Additional Staff:	Phone:

Emergency Contact List:

Backup Storage Facility:	Phone:
Backup Storage Facility:	Phone:
Electric Power Company:	Phone:
Refrigerator Repair Company:	Phone:
Temperature Alarm Monitoring Company:	Phone:
Transportation to Backup Storage:	Phone:
Emergency Generator Repair Company:	Phone:
National Weather Service:	Phone:

Vaccine Storage and Handling Events:

1. Determine the cause of improper vaccine temperatures (e.g., mechanical failure, power outage, natural disaster, human error).
2. Store the vaccines at appropriate temperatures. Determine if vaccine should be moved and move if appropriate.
3. Record the current temperature of the refrigerator/freezer.
4. Mark the vaccine so that the potentially compromised vaccines can be easily identified and not used until viability of vaccine is determined.
5. Collect essential data on the Emergency Vaccine Response Worksheet (attach additional copies if necessary).
6. Call the Iowa Immunization Program (1-800-831-6293).
7. Call all manufacturers of affected vaccine(s).

EMERGENCY VACCINE RESPONSE WORKSHEET

Clinic Name:		VFC PIN:
1. Date of event:		Handling Error:
2. Current temperature of refrigerator:		Max/min temperature reached:
3. Current temperature of freezer:		Max/min temperature reached:
4. Amount of time temperature was outside normal range: Refrigerator:		Freezer:

REFRIGERATOR	Vaccine/ Manufacturer	Lot Number	Expiration Date	Number of Doses	Opened Vials	Manufacturer Recommendations

FREEZER	Vaccine/ Manufacturer	Lot Number	Expiration Date	Number of Doses	Opened Vials	Manufacturer Recommendations

VACCINE MANUFACTURERS	Vaccine		Manufacturer	Phone
	IPOL, Tripedia, Daptacel, DT, Td(Tenivac), ActHib, Fluzone, Imogam (RIG), Imovax, Menomune, Typhim Vi, YF-VAX, Adacel, Menactra, Pentacel, Td (Decavac), Tubersol (PPD)		Sanofi Pasteur	1-800-822-2463
	Recombivax HB, MMR, Varivax, PedvaxHIB, Comvax, Pneumovax 23, Vaqta, RotaTeq, Gardasil, Zostavax, ProQuad		Merck	1-800-672-6372
	Infanrix, Pediarix, Engerix B, Havrix, Twinrix, Boostrix, Fluarix, Kinrix, Rotarix, FluLaval, Cervarix, Hiberix, Menhibrix		GlaxoSmithKline	1-888-825-5249
	Prevnar, Trumenba		Wyeth/Pfizer	1-800-999-9384
	Immune Globulin		Talecris	1-800-520-2807
	Nabi HB (Hep B Immune Globulin)		Nabi	1-800-458-4244
	Synagis, Flumist		MedImmune	1-877-633-4411
	RabAvert, Fluvirin, Agriflu, Menveo, Flucelvax		Novartis	1-800-244-7668
	Vivotif		Berna	1-800-533-5899
	Afluria		CSL Biotherapies	1-888-435-8633

VACCINE STORAGE AND HANDLING TRAINING LOG

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